DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

AUG - 8 2000

Rec'd AUG

Mr. Mark Gaeta
Chief Operating Officer
Country Life
180 Vanderbilt Motor Parkway
Hauppauge, New York 11788

Dear Ms. Gaeta:

This is in response to your letter to the Food and Drug Administration (FDA) dated July 25, 2000. In your letter, you stated that Country Life disagreed with our assertion that a claim cited by us in a letter dated July 17, 2000 was a disease claim that suggested that the product Country Life Rice Bran Oil softgels was a drug under the Federal Food, Drug, and Cosmetic Act (the Act).

In our July 25, 2000 letter, we stated that the claim "...helps maintain healthy cholesterol levels" suggested that the product Country Life Rice Bran Oil softgels was intended to treat, prevent, or mitigate disease. In your letter you stated that you disagreed with our assertion that this claim is a disease claim. You stated that your label claim was based on information contained in FDA's final rule on structure/function claims published in the January 6, 2000 Federal Register (65 FR 1000) which stated that a "claim that a substance helps maintain normal function would not ordinarily be a disease claim. Examples included: 'Helps maintain a healthy cholesterol level...' " (See 65 FR 1000 at 1015).

You are correct that in the April 29, 1998 proposed rule (63 FR 23624), FDA suggested that claims such as "helps maintain healthy cholesterol levels" might be appropriate structure function claims. However, in that proposal, FDA also asked for comments on whether it is appropriate to treat "maintains healthy cholesterol levels" as a permissible structure/function claim. After consideration of the comments received (see the discussion for comment 45 at 65 FR 1018), FDA concluded that references to "healthy" cholesterol may be misleading to consumers, and that an appropriate structure/function claim for maintaining cholesterol would be "helps to maintain cholesterol levels that are already within the normal range" [emphasis added]. Consequently, we continue to believe that the claim we cited in our July 17, 2000 letter to you, namely, "Rice bran oil helps maintain healthy cholesterol levels" is a disease claim.

975-0163

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, New York District Office, Compliance Branch, HFR-NE140

cc:
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (file, r/f)
HFS-811 (r/f, file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Betz)
GCF-1 (Nickerson, Dorsey)
f/t:rjm:HFS-811:RMoore:71831.adv:disc4

DESERT ESSENCE

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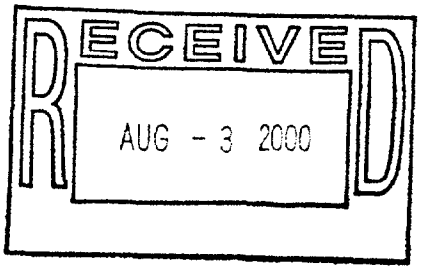
July 25, 2000



John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition

Dear Mr. Foret:

This is in response to your letter dated July 17, 2000, regarding the structure/function claim on the label of Country Life Rice Bran Oil softgels:

"Rice bran oil helps maintain healthy cholesterol levels"

This label claim was based on information printed in The Federal Register/Vol. 65, No. 4/Thursday, January 6, 2000/Rules and Regulations page 1015 (see attached). It clearly states that a substance which helps maintain normal function will not ordinarily be a disease claim. The example given in the Federal Register is:

"Helps maintain a healthy cholesterol level"

I would appreciate further communication on this matter. If upon further review, the structure/function claim is deemed inappropriate, Country Life will abide by the final decision.

Sincerely,

Mark Gaeta
Chief Operating Officer

180 Vanderbilt Motor Parkway, Hauppauge, New York 11788 • 516-435-8558 • Fax 516-232-5022

Federal Register

Thursday
January 6, 2000

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 101

Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Final Rule

(36.) A few comments addressed the examples of implied claims listed in the July 8, 1999, **Federal Register** notice. Some comments said that all of the examples were appropriate structure/function claims. Two comments suggested that "shrinks tumors," "prevents development of malignant tumors," and "prevents seizures" are express disease claims because they employ "synonyms" for specific diseases. According to these comments, "tumor" is a synonym for cancer, and "seizure" is a synonym for epilepsy. Another comment said that FDA should treat as implied disease claims only those claims "where there is a direct causal relationship between the structure/function parameter identified in the claim and a specific known disease." According to this comment, a tumor is a "direct manifestation of cancer" and therefore reference to a tumor is a disease claim. In contrast, risk factors for disease, in which the comment includes elevated cholesterol, are not direct manifestations of a disease, and therefore may be the subject of structure/function claims. Another comment contended that disease claims should be limited to express claims and to terms or measurements that are "surrogates for the disease itself." According to this comment, tumors are a surrogate for cancer, but elevated cholesterol is not a surrogate for heart disease. One comment argued that "relief of sneezing, runny nose, and itchy watery eyes caused by exposure to pollen or other allergens" is an acceptable structure/function claim, but did not explain why.

FDA has considered these comments, but does not believe that any of them have provided a principle that distinguishes between claims that consumers will understand as disease claims and those that will not be understood as disease claims. According to the comments, some of the claims that FDA offered as examples of implied disease claims should not be allowed as structure/function claims. FDA agrees that claims that refer to synonyms for disease, direct manifestations of disease, and surrogates for disease are disease claims. Each of these principles, however, would permit many types of implied disease claims that would be clearly understood by consumers as disease claims, e.g., "Herbal Prozac" and "antibiotic."

(37.) Some comments argued that it is impossible to construct a structure/function claim that does not imply disease prevention or treatment. Several of these comments claimed that health promotion claims inevitably imply disease prevention.

FDA does not agree that every structure/function claim implies disease prevention or treatment. In the proposed rule, FDA provided examples of many types of claims that the agency would not consider implied disease claims, and has expanded that list in the final rule.

(38.) Some comments disagreed with FDA's examples of disease claims in the proposed rule. These comments stated that intoxication and constipation are not in and of themselves diseases, and that these conditions are not readily understood by consumers as diseases. A few comments argued that alcohol intoxication is a "self-induced condition" and not a disease.

FDA continues to believe that alcohol intoxication, like all poisonings (mushroom, digitalis, or any drug overdose), meets the definition of disease, albeit a transient disease. The definition in § 101.14(a)(5), which FDA is incorporating in this rule, states, in part, that a disease is "damage to an organ, part or structure, or system of the body such that it does not function properly * * *" All poisonings, like alcohol intoxication, cause dose-related dysfunctioning and damage, ranging from mild impairments to death. Alcohol intoxication causes temporary damage to brain function, causing impairments of judgment, attention, reflexes, and coordination. The fact that it is "self-induced" does not remove it from the definition of disease. Deliberate barbiturate overdoses are also self-induced, but clearly meet the definition of disease.

FDA has considered the comments on constipation and agrees that certain constipation claims should not be treated as disease claims. Constipation has a variety of causes, many of them unrelated to disease. For example, constipation can be caused by changes in diet and schedule, and by travel. Constipation can also, however, be a symptom of such serious diseases as bowel obstruction and irritable bowel syndrome. FDA is aware that there may be differences of opinion about whether occasional constipation, alone, constitutes a disease, but believes that treating it as a disease would not be consistent with the intent of DSHEA. "For relief of occasional constipation" would therefore not be considered a disease claim under the rule. The labeling of a product that claimed to treat occasional constipation should make clear, however, that the product is not intended to be used to treat chronic constipation, which may be a symptom of a serious disease.

(39.) One comment questioned whether a claim that begins, "According to the National Cancer Institute" would be a disease claim because it used the word "cancer."

Although the National Cancer Institute (NCI) is associated with the treatment and prevention of cancer, such a statement will be considered a disease claim only if, within the context of the total labeling, the statement can be reasonably understood to relate the product to the disease listed in the organization's name, e.g., cancer. For example, FDA would regard as a disease claim "According to the National Cancer Institute, ingredient X protects smokers' lungs."

F. Signs or Symptoms of Disease (§ 101.93(g)(2)(ii))

Under proposed § 101.93(g)(2)(ii), a statement would be considered a disease claim if it explicitly or implicitly claimed an effect (using scientific or lay terminology) on one or more signs or symptoms that are recognizable to health care professionals or consumers as being characteristic of a specific disease or of a number of diseases. FDA provided as examples of such disease claims: "Improves urine flow in men over 50 years old," "lowers cholesterol," "reduces joint pain," and "relieves headache." Stating that claims of an effect on symptoms that are not recognizable as characteristic of a specific disease or diseases would not constitute disease claims, FDA provided the following examples of acceptable structure/function claims: "Reduces stress and frustration," "inhibits platelet aggregation," and "improves absentmindedness." The agency also stated that if the context did not suggest treatment or prevention of a disease, a claim that a substance helps maintain normal function would not ordinarily be a disease claim. Examples included: "Helps maintain a healthy cholesterol level," or "helps maintain regularity."

FDA specifically requested comment on the distinction between maintaining normal function, which is potentially the basis for an acceptable structure/function claim, and preventing or treating abnormal function, which is potentially a disease claim. FDA noted that the members of the Commission were divided on this issue, but that the final report concluded that "statements that mention a body system, organ, or function affected by the supplement using terms such as 'stimulate,' 'maintain,' 'support,' 'regulate,' or 'promote' can be appropriate when the statements do not suggest disease prevention or treatment or use for a serious health condition that is beyond the ability of the consumer to evaluate" (the report, p. 38). Recognizing that

claims relating to maintaining healthy cholesterol levels raise particularly difficult issues, FDA sought specific comment on these claims.

(40.) Many comments from manufacturers and individuals objected to proposed § 101.93(g)(2)(ii). Some of these comments argued that basing the criterion on which signs and symptoms were "recognizable" to health care professionals or consumers was too vague, and that it was unclear what proportion of health care professionals or consumers would be necessary to establish recognition. Some comments asked whether FDA expected manufacturers to conduct consumer surveys. Other comments urged that FDA itself conduct consumer surveys to determine which signs and symptoms were recognizable to consumers as implied disease claims. Other comments argued that the proposed provision would create a moving target because "as soon as consumers understood that certain signs and symptoms are characteristic of a disease—that is, as soon as consumers understood why they should take a particular supplement—FDA could * * * prohibit a product label from bearing the substantive claims information."

FDA agrees with these comments that the proposal's focus on recognition of signs and symptoms by consumers or health professionals might have made the provision difficult to apply, both for manufacturers and for the agency. Accordingly, the agency has substituted a more objective criterion. The final rule eliminates the reference to recognition, and focuses simply on whether the labeling suggests that the product will produce a change in the characteristic signs or symptoms of a specific disease or class of diseases. FDA believes that it will be easier for manufacturers to verify whether symptoms are in fact characteristic of a disease. FDA and manufacturers may look to medical texts and other objective sources of information about disease to determine whether a label implies treatment or prevention of disease by listing the characteristic signs and symptoms of a disease or class of diseases.

FDA notes that the standard in the rule may be met if characteristic signs and symptoms are referred to either in technical or lay language. It also would not be necessary to mention every possible sign or symptom of a disease to meet this standard. Instead, the standard focuses on whether the labeling suggests that the product will produce a change in a set of one or more signs or symptoms that are characteristic of the disease.

FDA does not agree with the comment that objected to the recognition standard because it would prohibit a claim "as soon as consumers understood that certain signs and symptoms are characteristic of a disease—that is, as soon as consumers understood why they should take a particular supplement * * *." This comment assumes that the only reason people take dietary supplements is to treat or prevent disease and that it is appropriate to market supplements by implying that they can do so. Many people take dietary supplements for health-related reasons that do not involve treatment or prevention of specific diseases. As discussed elsewhere in this document, FDA does not believe that the act permits structure/function claims to imply treatment or prevention of specific diseases.

(41.) Several comments contended that the recognition standard was too restrictive because all signs or symptoms relating to the structure or function of the body are potentially recognizable to health care professionals and educated consumers as characteristic of some specific disease. Another comment argued that the proposal to treat references to signs and symptoms as disease claims was arbitrary and artificial. The comment said that specific examples of disease claims used in the proposal could as easily refer to nondisease states, e.g., "reduces joint pain" could refer to over-exercise. Conversely, "stress and frustration" could refer to anxiety and depression. Another comment contended that "reduces joint pain" is an acceptable structure/function claim if other language or graphics in the labeling clearly communicated treatment of conditions unrelated to arthritis. One comment asked whether "helps support cartilage and joint function" would constitute a permissible structure/function claim. Some comments said that references to signs and symptoms should not be evidence of a disease claim because signs and symptoms can be associated with a number of varying conditions. One comment claimed that "inhibits platelet aggregation" does not mean anything to most consumers. On the other hand, some medical groups, groups devoted to specific diseases, and others expressed concern that the examples of structure/function claims provided by FDA permitted references to signs or symptoms that imply disease treatment or prevention. According to one comment, "inhibits platelet aggregation" could be interpreted to mean "prevents heart attack," and "improves absentmindedness" could be interpreted as a treatment for Alzheimer's disease.

FDA believes that removing the reference to recognition by consumers or health professionals from § 101.93(g)(2)(ii) will permit a clearer distinction between those signs and symptoms that imply a disease and those that do not. The focus will be on whether specific signs or symptoms are characteristic of a disease, based on objective sources. FDA does not believe that "improves absentmindedness" or "relieves stress and frustration" are characteristic of the specific diseases mentioned in the comments. FDA agrees that some signs and symptoms are associated with such a wide variety of diseases and nondisease states that they may not imply a specific disease or class of diseases. For example, FDA would not interpret "improves absentmindedness" as implying treatment of Alzheimer's disease because absentmindedness is not as serious as the type of memory loss characteristically suffered by Alzheimer's patients; absentmindedness is, in fact, suffered predominantly by people who do not have Alzheimer's disease or any other disease. Stress and frustration, while associated with some anxiety disorders, are not the characteristic symptoms of those disorders; in addition, these symptoms are equally associated with many other nondisease states.

The agency does agree, however, with the comment that "inhibits platelet aggregation" is an implied disease treatment or prevention claim. Although platelet aggregation is a normal function needed to maintain homeostasis, inhibiting or decreasing platelet aggregation is a well-recognized therapy for the prevention of stroke and recurrent heart attack (see, e.g., 63 FR 56802, October 23, 1998 (final rule for professional labeling of aspirin for cardiovascular, cerebrovascular, and rheumatologic uses); 53 FR 46204, November 16, 1988, (internal analgesic tentative final monograph)). Inhibiting or decreasing platelet aggregation is the mechanism of action of a number of drug products approved for the treatment or prevention of stroke and heart attack. Thus, the agency would consider a claim to inhibit normal platelet function to be an implied claim to treat or prevent these disease conditions.

FDA also believes that "joint pain" is characteristic of arthritis. According to the Merck Manual, joint tenderness is the most sensitive physical sign of rheumatoid arthritis (Ref. 6). The claim "helps support cartilage and joint